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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,778	08/21/2001	Rodney B. Croteau	WSUR117920	9476

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EXAMINER	
LU, FRANK WEI MIN	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/934,778	CROTEAU ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2005* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,17,18 and 42-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,18 and 43* is/are rejected.

7)☒ Claim(s) *17, 42, and 44* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of RCE and the response filed on April 8, 2005 have been entered. The claims pending in this application are claims 10, 17, 18, and 42-44. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the response. The following rejections are based on the response filed on April 8, 2005 and claims 10, 17, 18, and 42-44 will be examined.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 10 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for encoding an isolated, recombinant *Mentha piperita* geranyl diphosphate synthase large subunit protein using a nucleic acid molecule consisting of SEO ID NO:1 and encoding an isolated, recombinant *Mentha piperita* geranyl diphosphate synthase small subunit protein using a nucleic acid molecule consisting of SEO ID NO:10, does

not reasonably provide enablement for encoding an isolated, recombinant geranyl diphosphate synthase large subunit protein using any kind of nucleic acid molecule that hybridizes to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEQ ID NO:1 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 1 X SSC at 55 °C for 30 minutes and encoding an isolated, recombinant geranyl diphosphate synthase small subunit protein using any kind of nucleic acid molecule that hybridizes to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEO ID NO:10 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 0.5 X SSC at 55 °C for 30 minutes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, there is no direction or guidance in the specification to show that any kind of nucleic acid molecule that hybridizes to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEO ID NO:1 under conditions of 5 X SSC at 65 °C for 16

hours followed by one wash in 1 X SSC at 55 °C for 30 minutes can encode an isolated, recombinant geranyl diphosphate synthase large subunit protein and any kind of nucleic acid molecule that hybridizes to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEO ID NO:10 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 0.5 X SSC at 55 °C for 30 minutes can encode an isolated, recombinant geranyl diphosphate synthase small subunit protein. While the relative skill in the art is very high (the Ph.D. degree with laboratory experience), there is no predictability whether any kind of nucleic acid molecule recited in claims 10 and 18 can encode an isolated, recombinant geranyl diphosphate synthase large subunit protein and an isolated, recombinant geranyl diphosphate synthase small subunit protein.

Claims 10 and 18 are directly to an isolated, recombinant geranyl diphosphate synthase large subunit protein from any source and an isolated recombinant geranyl diphosphate synthase protein from any source comprising an isolated, recombinant geranyl diphosphate synthase large subunit protein and an isolated, recombinant geranyl diphosphate synthase small subunit protein. The specification only show that a nucleic acid molecule consisting of SEQ ID NO: 1 can encode an isolated, recombinant *Mentha piperita* geranyl diphosphate synthase large subunit protein (SEQ ID NO: 2) and a nucleic acid molecule consisting of SEQ ID NO: 10 can encode an isolated, recombinant *Mentha piperita* geranyl diphosphate synthase small subunit protein (SEQ ID NO: 11). However, the specification does not provide a guidance to show that any kind of nucleic acid molecule that hybridizes to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEO ID NO:1 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 1 X SSC at 55 °C for 30 minutes can encode an isolated,

recombinant geranyl diphosphate synthase large subunit protein and any kind of nucleic acid molecule that hybridizes to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEO ID NO:10 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 0.5 X SSC at 55 °C for 30 minutes can encode an isolated, recombinant geranyl diphosphate synthase small subunit protein. In fact, an oligonucleotide from nucleotides 109657 to 109673 of negative strand of Streptomyces coelicolor A3 (2) complete genome that is 100% identical to nucleotides 226-242 of SEQ ID NO:1 and can hybridizes to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEO ID NO:1 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 1 X SSC at 55 °C for 30 minutes can not encode an isolated, recombinant geranyl diphosphate synthase large subunit protein (see attached sequence matches between SEQ ID NO: 1 and nucleotides 109657 to 109673 of negative strand of Streptomyces coelicolor A3 (2) complete genome) and an oligonucleotide from nucleotides 532-548 of negative strand of Gallus gallus finished cDNA that is 100% identical to nucleotides 702-718 of SEQ ID NO:10 and can hybridize to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEO ID NO:10 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 0.5 X SSC at 55 °C for 30 minutes can not encode an isolated, recombinant geranyl diphosphate synthase large subunit protein (see attached sequence match between SEQ ID No: 10 and nucleotides 532-548 of negative strand of Gallus gallus finished cDNA). Therefore, it is unclear whether all nucleic acids recited in claims 10 and 18 can encode an isolated, recombinant geranyl diphosphate synthase large subunit protein and an isolated, recombinant geranyl diphosphate synthase small subunit protein.

With these unpredictable factors, the skilled artisan will have no way to predict the experimental results. Accordingly, it is concluded that undue experimentation is required to make the invention as it is claimed. These undue experimentation at least includes to test whether any nucleic acid recited in claims 10 and 18 can encode an isolated, recombinant geranyl diphosphate synthase large subunit protein and an isolated, recombinant geranyl diphosphate synthase small subunit protein.

Response to Arguments

In page 1, third paragraph bridging to page 5, second paragraph of applicant's remarks, applicant argues that, in view of the teachings in Examples 1 and 6 of the specification, one of ordinary skill in the art can use the teachings of the present application to readily identify and isolate nucleic acid molecules that hybridize to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEQ ID NO: 1 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 1 X SSC at 55 °C for 30 minutes, and readily identify and isolate nucleic acid molecules that hybridize to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEQ ID NO: 10 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 0.5 X SSC at 55 °C for 30 minutes. One of ordinary skill in the art can further use the teachings of the present application to readily determine whether the isolated nucleic acid molecule encodes a geranyl diphosphate synthase large subunit protein or a geranyl diphosphate synthase small subunit protein.

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, since claims 1 and 10 are directly to an isolated, recombinant geranyl diphosphate synthase large subunit protein from any source and an isolated recombinant

geranyl diphosphate synthase protein from any source comprising an isolated, recombinant geranyl diphosphate synthase large subunit protein and an isolated, recombinant geranyl diphosphate synthase small subunit protein, not every nucleic acid molecule recited in claim 1 or claim 10 that hybridizes to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEQ ID NO: 1 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 1 X SSC at 55 °C for 30 minutes can encode an isolated, recombinant geranyl diphosphate synthase large subunit protein and not every nucleic acid molecule recited in claim 10 that hybridizes to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEQ ID NO: 1 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 0.5 X SSC at 55 °C for 30 minutes can encode an isolated, recombinant geranyl diphosphate synthase small subunit protein. In fact, an oligonucleotide from nucleotides 109657 to 109673 of negative strand of Streptomyces coelicolor A3 (2) complete genome that is 100% identical to nucleotides 226-242 of SEQ ID NO:1 and can hybridizes to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEO ID NO:1 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 1 X SSC at 55 °C for 30 minutes can not encode an isolated, recombinant geranyl diphosphate synthase large subunit protein (see attached sequence matches between SEQ ID NO: 1 and nucleotides 109657 to 109673 of negative strand of Streptomyces coelicolor A3 (2) complete genome) and an oligonucleotide from nucleotides 532-548 of negative strand of Gallus gallus finished cDNA that is 100% identical to nucleotides 702-718 of SEQ ID NO:10 and can hybridize to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEO ID NO:10 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 0.5 X SSC at 55 °C

for 30 minutes can not encode an isolated, recombinant geranyl diphosphate synthase large subunit protein (see attached sequence match between SEQ ID No: 10 and nucleotides 532-548 of negative strand of Gallus gallus finished cDNA). Therefore, it is unclear whether all nucleic acids recited in claims 10 and 18 can encode an isolated, recombinant geranyl diphosphate synthase large subunit protein and an isolated, recombinant geranyl diphosphate synthase small subunit protein. Second, applicant does not provide evidence to show that every nucleic acid molecule recited in claim 1 or claim 10 that hybridizes to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEQ ID NO: 1 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 1 X SSC at 55 °C for 30 minutes can encode an isolated, recombinant geranyl diphosphate synthase large subunit protein and every nucleic acid molecule recited in claim 10 that hybridizes to the complement of a nucleic acid molecule consisting of the nucleic acid sequence set forth in SEQ ID NO: 1 under conditions of 5 X SSC at 65 °C for 16 hours followed by one wash in 0.5 X SSC at 55 °C for 30 minutes can encode an isolated, recombinant geranyl diphosphate synthase small subunit protein.

4. Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To the extent that the claimed composition/or methods are not described in the instant disclosure, claim 43 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

Although the specification describes that SEQ ID NO: 2 (see sequencing listing), the specification fails to define "a transit peptide" in the specification. Furthermore, in applicant's remarks filed on September 7, 2004 and April 8, 2005, applicant does not indicate which part in the specification supports such claim limitation.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

Response to Arguments

In page 5, last paragraph bridging to page 6, second paragraph of applicant's remarks, applicant argues that "[A]pplicants submit that the instant application clearly discloses and claims SEQ ID NO:2, which is an example of an isolated recombinant geranyl diphosphate synthase large subunit protein of Claim 10 comprising a transit peptide consisting of amino acids 1-40 of SEQ ID NO:2. One of ordinary skill in the art would readily recognize that applicant is in possession of the subject matter of Claim 43, and that the subject matter of Claim 43 is part of the invention. Thus, applicants submit that the subject matter of Claim 43 is described by the instant specification".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection because there is no phrase "transit peptide" in the specification. Furthermore, in applicant's remarks filed on September 7, 2004 and April 8, 2005, applicant does not indicate which part in the specification supports such claim limitation.

Claim Rejections - 35 USC § 101/112

5. Claim 43 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claims 43 is directed to an isolated recombinant geranyl diphosphate synthase large subunit protein comprising a transit peptide consisting of amino acids 1 through 40 of SEQ ID NO:2.

The specification only discloses that SEQ ID NO: 2 is *Mentha piperita* geranyl diphosphate synthase large subunit protein (see Sequencing Listing). However, the specification does not provide evidence to support that a polypeptide comprising a transit peptide consisting of amino acids 1 through 40 of SEQ ID NO:2 must encode a geranyl diphosphate synthase large subunit protein and has the same function as geranyl diphosphate synthase large subunit protein. A substantial utility is a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. Absence of the function of the claimed polypeptide, no "real world" use of the claimed polypeptide has been established. The asserted utility for the claimed polypeptide does not appears to be specific and substantial because it is unclear whether claimed polypeptide has the same function of SEQ ID NO:2. Thus, the specification fails to support and provide

evidence for a specific and substantial utility or a well-established utility of the claimed polypeptide.

Claim 43 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Since the specification fails to show that that a polypeptide comprising a transit peptide consisting of amino acids 1 through 40 of SEQ ID NO:2 must encode a geranyl diphosphate synthase large subunit protein and it is unclear whether claimed polypeptide has the same function of SEQ ID NO:2. Thus, function of the polypeptide encompassed by the claim is highly unpredictable. In view of the unpredictability of claimed polypeptide, one skilled in the art at the time of the invention would not know how to use the claimed polypeptide.

For the reasons discussed above, it would have required undue experimentation for one skilled in the art at the time of the invention to practice over the full scope of the invention claimed. This is particularly true given the nature of the invention, the state of the prior art, the breadth of the claims, the amount of experimentation necessary, the working examples provided and scarcity of guidance in the specification, and the unpredictable nature of the art. The undue experimentation at least includes to test whether claimed polypeptide has the same function as SEQ ID NO: 2.

Response to Arguments

In page 5, third paragraph of applicant's remarks, applicant argues that "[A]pplicants submit that there is no requirement that amino acids 1-40 of SEQ ID NO:2 can perform the same

function as SEQ ID NO:2. Amino acids 1-40 of SEQ ID NO: 2 comprise a transit peptide that directs a protein attached to the peptide to a cellular membrane. In contrast, SEQ ID NO:2, that includes the transit peptide, is a geranyl diphosphate synthase large subunit protein that catalyzes the formation of geranyl diphosphate synthase".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. Since the specification does not provide evidence to support that a polypeptide comprising a transit peptide consisting of amino acids 1 through 40 of SEQ ID NO:2 must encode a geranyl diphosphate synthase large subunit protein and has the same function as geranyl diphosphate synthase large subunit protein, a polypeptide comprising a transit peptide consisting of amino acids 1 through 40 of SEQ ID NO:2 is highly unpredictable. Therefore, the specification fails to support and provide evidence for a specific and substantial utility or a well-established utility of the claimed polypeptide, and one skilled in the art clearly would not know how to use the claimed polypeptide.

Conclusion

6. Claims 17, 42, and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. No claim is allowed.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30

(November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
April 29, 2005

FRANK LU
PATENT EXAMINER